UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

07 CV 7424

CLYDE OWEN,

Plaintiff

v.

BRISTOL-MYERS SQUIBB COMPANY, and SCHERING CORPORATION,

Defendants.

Civil Action No.

COMPLAINT AND DEMAND FOR JURY TRIAL

COMES NOW Plaintiff, Clyde Owen, ("Plaintiff"), by and through his undersigned counsel, and sets forth his Complaint for damages against the Defendant as follows:

NATURE OF THE ACTION

1. This is an action to recover damages for personal injuries suffered by Clyde Owen as a direct and proximate result of the Defendants', Bristol-Myers Squibb Company (hereinafter referred to as "BMS") and Schering Corporation (hereinafter referred to as "Schering"), (collectively referred to as "Defendants"), negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, advertising, promoting, marketing, distribution, labeling, and/or sale of the antibiotic Tequin (also known as "Gatifloxacin"). Mr. Owen brings this claim for strict liability, negligence, breach of implied warranty for fitness, breach of implied warranty for merchantability, fraudulent misrepresentation, fraudulent concealment, intentional infliction of emotional distress, violation of Arkansas Consumer Protection Act and Unfair Deceptive Trade Practices and punitive damages.

2. Based upon information and belief Defendants also willfully with knowledge, recklessly without knowledge, or mistakenly misrepresented material facts regarding the safety and efficacy of Tequin and such misrepresentations were innocently acted on by Plaintiff in taking Tequin.

3. At all times material hereto, Defendants marketed and sold a product, Tequin, that was not reasonably safe when applied to its intended use in the usual and customary manner.

4. At all times material hereto, Defendants' product, Tequin, was defective and/or unreasonably dangerous.

5. At all times material hereto, Defendants designed, developed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled, and/or sold Tequin in the State of Arkansas.

6. At all times material hereto, Defendants failed to provide any, or adequate, warnings to doctors and consumers that taking Tequin could cause, and significantly increase the risk of: diabetes, severe hyperglycemia, and severe hypoglycemia.

PARTIES

7. This is an action for damages which exceeds the minimum jurisdictional limits of this Court. Plaintiff currently resides in Beaufort, in Beaufort County, South Carolina. Further, at all times relevant, Plaintiff was a resident of Searcy, Arkansas, in Searcy County, is over 21 years of age, ingested Tequin, and was injured in the State of Arkansas as a result of Defendants' actions inside and/or outside the state of Arkansas and New York.

8. The Defendant, Bristol-Myers Squibb Company, is a Delaware corporation with its principal place of business in New York. At all times material hereto, this Defendant was in the business of manufacturing, promoting, marketing, developing, supplying, labeling, testing, selling, and/or distributing the antibiotic Gatifloxacin, also known as Tequin, in the State of Arkansas.

9. The Defendant, Schering Corporation, is a Florida corporation with its principal place of business in New Jersey. At all times material hereto, this Defendant was in the business of marketing, promoting, selling and/or distributing the antibiotic Tequin in the State of Arkansas. In addition, at all times material hereto, Schering was a licensed pharmaceutical distributor of Tequin within the State of Arkansas.

GENERAL ALLEGATIONS

10. Defendants placed a defective and unreasonably dangerous product, Tequin, on the market.

11. As a result of taking Tequin, Plaintiff developed severe symptoms of hyperglycemia and was hospitalized. During his hospitalization, Plaintiff was diagnosed with severe hyperglycemia and new onset of Diabetes Mellitus. Today the Plaintiff continues to suffer from Diabetes Mellitus induced by his Tequin ingestion.

12. Defendants directly or indirectly, negligently and/or defectively made, created, manufactured, assembled, designed, tested, labeled, supplied, packaged, distributed, marketed, advertised, warned, and/or sold in the State of Arkansas, the antibiotic Tequin.

13. Defendants had control of the design, assembly, packaging, marketing, advertising, manufacturing, labeling, testing, promoting, and/or sale of the antibiotic Tequin.

14. At all times material hereto, the Defendants herein either knew or should have known that the drug was related to and associated with severe and life threatening complications and side effects including but not limited to, dysglycemic events, such as hypoglycemia and hyperglycemia.

15. Although Defendants knew or should have known of the dangerous risks associated with the use of Tequin, Defendants proceeded to or permitted the drug to be advertised, promoted and/or sold without adequate warnings of the seriousness of the side effects and significance of the increased risk of injury.

16. Tequin was approved by the Food and Drug Administration ("FDA") of the United States on December 17, 1999, and was subsequently introduced into the stream of commerce in the United States market.

17. Tequin is an antibiotic in a class of at least seven fluoroquinolones used to treat a variety of infections, including, but not limited to, lung, sinus, skin and/or urinary tract infections and certain sexually transmitted diseases, such as gonorrhea and syphilis.

18. Tequin offers no unique benefit over the other fluoroquinolones; however, it is associated with unique, severe, life-threatening risks that are not associated with many other fluoroquinolones.

19. Defendants represented to the public that Tequin was as safe and effective as other fluoroquinolones. Defendants failed to make sufficient changes in these representations, labeling, or physician communications to distinguish Tequin from other fluoroquinolones and to alert health care providers and patients that Tequin had special or unique risks.

20. In 2001, case reports of Tequin-associated dysglycemia in both diabetics and non-diabetics were being published in medical literature. It was not until October 2002, that BMS changed the Tequin label to include any information about gatifloxacin-associated dysglycemic risks. Even then, the labeling changes were inadequate and downplayed the severity and level of risk of dysglycemia associated with Tequin.

21. In 2003, in the Canadian Adverse Reaction Newsletter, it was reported that after a review of Health Canada's database of spontaneous reports, from February 2001 to February 2003, there was an indication that hyperglycemia and hypoglycemia were reported more frequently with Tequin than with other quinolones. Specifically, there were 28 serious reports of abnormal glucose metabolism associated with Tequin, 19 hospitalizations, and two deaths.

22. In 2003, the drug was contraindicated in Japan for diabetics; however, no such contraindication appeared in the United States label until February of 2006.

23. Despite the data available to the Defendants, they failed to adequately alter the drug inserts and/or labeling and/or promoting to indicate the severe risks, and potentially fatal, dysglycemic reactions. While the aforementioned studies and data (dating back to 2002) indicated a strong correlation between Tequin patients with diabetes and the adverse reaction of severe hypoglycemia, the labeling change by BMS in January 2004 did not adequately address the seriousness of this adverse reaction or the significance of the increased risk.

24. Defendant BMS revised its package insert four times, however, at no time did the insert adequately address and clarify the drug's tendency to cause severe dysglycemic reactions. It merely referred to the reaction as a "disturbance" in blood glucose,

effectively deluding doctors and patients into thinking that Tequin was safe. Moreover, BMS's label discounted and diluted (1) existing studies and articles associating Tequin with severe dysglycemia; and (2) its own references to blood glucose disturbances in its label.

25. As Frothingham reported in his Glucose Homeostasis Abnormalities Associated with Use of Gatifloxacin study in November of 2004, an official publication of the Infectious Diseases Society of America, there was a 56-fold increase in severe glucose homeostasis abnormalities and gatifloxacin-associated dysglycemia.

26. On February 15, 2006, Defendant BMS revised the labeling of Tequin contraindicating the drug for use in diabetic patients. Additionally, the Defendant strengthened the warning in reference to dsyglycemia and included other risk factors. However, as alleged in the Public Citizen petition, filed May 1, 2006, this fourth label change was also an insufficient remedial action for a drug that carries a unique risk without a unique clinical benefit as compared to the other fluoroquinolones. Moreover, in this fourth label change, Defendant again did not warn of the risk of developing diabetes.

27. Upon information and belief, on February 15, 2006, despite changing its new labels to include a contraindication for diabetics, the Defendants did not provide a timely warning to those who had recently purchased or been prescribed Tequin.

28. On March 1, 2006, a study by Park-Wyllie, et al, published in the New England Journal of Medicine showed that all patients (diabetic or non-diabetic) having received Tequin had approximately 17 times the odds of having a hyperglycemic episode and 4 times the odds of having a hypoglycemic episode compared with other antibiotics. Again, the data used in this study was available to Defendants as early as April 2002.

29. At no time did the Defendants warn consumers or physicians of the risk of Tequin causing diabetes.

30. On May 2, 2006, Defendant BMS quietly announced to its shareholders that it would no longer manufacture Tequin for economic reasons. However, this notice is grossly inadequate and does nothing to protect the public's health given the data that is known and because there is no intention by the defendants to stop selling the drug already in the channels of commerce.

31. The representations made by the Defendants were false and misleading and allowed the continuation of treatment of patients with Tequin and subsequent harm to numerous patients. Moreover, by making such representations the Defendants have concealed the facts giving rise to Tequin patients' causes of action, including the facts involved in this Plaintiff's claims.

32. On or about July, 2005, Plaintiff Clyde Owen was given Tequin by his physician.

33. Plaintiff, Clyde Owen, took Tequin on or about July, 2005 and continued to take it for approximately one week. Shortly following his ingestion of Tequin, Mr. Owen began experiencing symptoms of hyperglycemia, including dizziness, anxiety, confusion, irregular heartbeat, numbness and tingling of extremities and other elements of feeling poorly.

34. Within days to weeks following his ingestion of Tequin, Mr. Owen's doctor diagnosed him with Diabetes Mellitus.

35. Prior to taking Tequin the Plaintiff did not have any symptoms related to hyperglycemia or diabetes and instead was a healthy, active person.

36. As a direct and proximate result of Defendants placing the drug into the stream of commerce, Plaintiff suffered an injury and developed a severe and life threatening illness and continues to suffer from Diabetes Mellitus to this day.

37. Plaintiff has also incurred significant medical, hospital, and/or pharmaceutical expenses and/or other economic loss and will continue to incur such expenses and losses as a result of the Defendants' conduct.

38. Upon information and belief the Defendants co-promoted and marketed Tequin. In conjunction with this agreement, false, diluted and/or fraudulent information was provided to pharmacists, consumers, and prescribing physicians about the risks and supposed benefits of this drug. Upon information and belief, and in furtherance of the co-promotion, the Defendants supplied false and misleading marketing and promoting material and programs to unsuspecting pharmacists and prescribing physicians. As a result of the sales of Tequin, Defendants reaped profits and sales of Tequin within Arkansas.

39. Upon information and belief, the co-promotional pieces contained false and fraudulent misrepresentations regarding the safety and efficacy of Tequin. Thus, Defendants affirmatively assumed a duty to detect and warn consumers and their doctors, including Plaintiff and his doctor, and Plaintiff reasonably relied upon those representations to his detriment in taking Tequin. Defendants breached that duty when they marketed, promoted, and/or sold drugs to the Plaintiff and his doctor without adequately warning them about the dangers associated with the use of Tequin.

COUNT I
STRICT LIABILITY
IN VIOLATION OF ARKANSAS CODE § 16-116-101, *et seq.*

40. Plaintiff repeats, reiterates and realleges the allegations set forth in paragraphs 1 through 39 above, with the same force and effect as if fully set forth herein.

41. Defendants are strictly liable for violating Arkansas product liability law as set forth in section Arkansas Code § 16-116-101, *et. seq.*, because it defectively designed, and/or defectively manufactured Tequin and/or failed to adequately warn consumers and physicians of the risks associated with Tequin.

42. The drug, Tequin, was defective and created an unreasonably dangerous condition when it was produced by and left the possession of the Defendants in that it significantly increased the risk of and caused severe and life threatening complications and side effects, including, but not limited to, dysglycemic events such as hyperglycemia, hypoglycemia, diabetes, diabetic coma, diabetic hyperglycemic coma, diabetic hyperosmolar coma, diabetic ketoacidosis, hypoglycemic coma, and hyperosmolar state.

43. Plaintiff used the drug for its intended purpose, i.e. – to fight an infection and get well.

44. The facts are such that the Plaintiff could not have discovered the defect in Tequin through the exercise of reasonable care and had no way of realizing its dangerous condition.

45. Unlike the Plaintiff, the Defendants, as manufacturers and distributors of a prescription drug, is held to the level of knowledge of an expert in the field.

46. The prescribing physician did not have substantially the same knowledge of the defect as the Defendants.

47. Defendants failed to provide to the prescribing physician a warning that accurately or adequately communicated the level of increased risk of severe dysglycemia to patients including diabetic patients.

48. The warnings that were given by the Defendants to the prescribing physicians were not accurate, clear, and/or were vague and ambiguous.

49. The Defendants had a continuing duty to warn the Plaintiff and/or the prescribing physicians of the dangers associated with the drug, current research identifying increased risks of injury, and contraindications for diabetic patients.

50. Defendant, BMS, failed to provide a reasonably safe alternative formulation of the drug when Defendant BMS knew or should have known that other antibiotics were available and existing in the market which could fight infection in patients without subjecting them to the risk which Tequin subjected the patient.

51. At all times material to this action, Defendants engaged in the business of designing, distributing, supplying manufacturing, marketing, promoting and/or selling the drug Tequin, which is defective and created an unreasonably dangerous condition to consumers, including Plaintiff, when put to its intended use.

52. At all times material to this action, Tequin was designed, sold, distributed, supplied, manufactured, marketed and/or promoted by Defendants was expected to reach, and did reach, consumers in the State of Arkansas, including Plaintiff, without substantial change in the condition in which it was sold.

53. At all times material to this action, Tequin was designed, sold, marketed, distributed, supplied, manufactured and/or promoted by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce.

54. At the time Tequin left the possession of the Defendants, the product was defective and created an unreasonably dangerous condition when it was designed, manufactured, marketed, packaged and labeled by the Defendants in that, among other ways:

a. It caused injury to the user far beyond any warned, noticed, expected or reasonable side effect or adverse reaction and when placed in the stream of commerce it contained unreasonably dangerous defects subjecting Plaintiff to risks from expected or known usage, including bodily injury, which exceeded the benefits of the drug;

b. When placed in the stream of commerce it was defective in design and formulation making use of the drug more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with the taking of equivalent antibiotics;

c. It contained insufficient and/or ineffective warnings to alert consumers and users to the risks of injury and death by dysglycemia including hyperglycemia, hypoglycemia, diabetes, and other serious side effects or reactions;

d. The drug caused harmful side effects which outweighed its potential utility;

e. It was insufficiently tested;

f. There were insufficient instructions on the proper use of the drug;

g. There was misleading advertising and promotion concerning the safety and benefits of using the drug;

h. There were inadequate post-marketing warnings or instructions because, after the Defendants knew or should have know of the significant risks previously described, the Defendants failed to provide adequate warnings to users and consumers, and/or their physicians, and continued to promote the sale and use of the drug;

i. The aforesaid drug had not been materially altered or modified prior to the use of said drug by Plaintiff;

j. The drug was not accompanied by adequate instructions and/or warning to apprize consumers, including Plaintiff, or their doctors, of the full nature or extent of the risks and side effects associated with the use of Tequin, thereby rendering Defendants liable to Plaintiff pursuant to the relevant sections of Arkansas Product Liability Act; and

k. Defendants placed Tequin in the stream of commerce when they knew or should have known that Tequin posed a substantial risk of harm to consumers utilizing Tequin.

55. As a direct and proximate result of the defective and unreasonably dangerous condition of the drug, Plaintiff suffered significant physical injuries and endured substantial pain and suffering. He incurred expenses for medical treatment, loss of capacity for the enjoyment of life and other losses and damages recognized by Arkansas law. Plaintiff has been physically, emotionally, and economically injured and seeks all damages recoverable by law from the Defendants, as alleged herein.

56. WHEREFORE, Plaintiff demands judgment against Defendants for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

COUNT II
NEGLIGENCE

57. Plaintiff repeats, reiterates and realleges the allegations set forth in paragraphs 1 through 56 above, with the same force and effect as if fully set forth herein.

58. Defendants negligently[1] caused the Plaintiff harm.

59. Defendants directly or indirectly, negligently and/or defectively made, created, manufactured, assembled, designed, tested, labeled, supplied, packaged, distributed, promoted, marketed, advertised, warned, and/or sold, in the State of Arkansas, the drug Tequin.

60. At all times material hereto, Defendants had a duty to Plaintiff to exercise reasonable care in design, manufacture, testing, processing, advertising, marketing, testing, labeling, assembling, packaging, distribution, promotion, sale and warning related its respective drug.

61. Defendants breached that duty and was negligent in its actions, misrepresentations, and/or omissions toward Plaintiff in the following ways:

a. Failed to include accurate and adequate warnings with the drug that would alert consumers and physicians to the level of risks and seriousness of side affects of the drug of which it had actual or constructive knowledge;

b. Failed to adequately and properly test the drug before placing the drug on the market;

c. Failed to conduct sufficient testing on the drug which, if properly performed, would have shown that the drug had serious side effects, including, but not limited to, severe dysglycemia;

[1] *Jordan, et al. v. Adams*, 259 Ark. 407 (1976); *Mason v. Jackson*, 323 Ark. 252 (1996).

d. Failed to adequately warn Plaintiff and the prescribing physicians that use of the drug carried risk of severe and life threatening disability due to dysglycemia;

e. Failed to warn Plaintiff and the prescribing physician that use of the drug carried a risk that hospitalization may become necessary to correct the severe blood glucose disturbances;

f. Failed to provide adequate post-marketing warning or instructions after the Defendants knew or should have known of the significant risks of severe and life-threatening dysglycemia from the use of the drug;

g. Failed to adequately warn the Plaintiff and the prescribing physician that the drug could cause hypoglycemia, hyperglycemia and diabetes;

h. Failed to adequately warn the Plaintiff and prescribing doctors that the drug product could create a significantly increased risk of disturbed glucose homeostasis in patients without diabetes;

i. Encouraged use while underplaying the side effects to doctors and the public in order to make a profit from sales.

62. Defendants knew or should have known that the drug caused unreasonably dangerous risks and serious side effects of which the Plaintiff and the prescribing physician would not be aware. Defendants nevertheless advertised, marketed, sold and/or distributed the drug knowing that there were safer alternatives and products to treat the same infection.

63. As a direct and proximate result of the negligence of the Defendants, Plaintiff suffered significant physical injuries and endured substantial pain and suffering. He incurred expenses for medical treatment, loss of capacity for the enjoyment of life and other

losses and damages recognized by Arkansas law. Plaintiff has been physically, emotionally, and economically injured and seeks all damages recoverable by law from Defendants, as alleged herein.

64. WHEREFORE, Plaintiff demands judgment against the Defendants for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

COUNT III
BREACH OF IMPLIED WARRANTY OF FITNESS

65. Plaintiff repeats, reiterates and realleges the allegations set forth in paragraphs 1 through 64 above, with the same force and effect as if fully set forth herein.

66. The Defendants violated the implied warranty of fitness for particular purpose under Arkansas law.[2]

67. Defendants had reason to know that the Plaintiff and his doctor needed to use its product for the safe and efficient treatment of infection and illness. Moreover, the Defendants had reason to know that both the Plaintiff and his doctor were relying on the Defendants' skill and/or judgment to select and/or furnish suitable goods.

68. When Defendants placed the drug into the stream of commerce, they knew of the use for which the drug was intended and impliedly warranted the product to be safe and fit for such use and purpose.

69. Plaintiff and his doctor reasonably relied upon the expertise, skill, judgment and knowledge of Defendants and upon the implied warranty that the drug was fit for use for the safe treatment of infection.

70. Because of his infection, the Plaintiff was a person whom the Defendants would have reasonably expected to use Tequin.

[2] *E.I. Du Pont de Nemours & Co. v. Dilaha*, 280 Ark. 477, 480 (Ark. 1983); *see also Woods v. Hopmann Machinery, Inc.* 301 Ark. 134, 138(Ark. 1990).

71. The drug was not safe or fit for its intended use because the product was and is unreasonably dangerous and unfit for the ordinary purposes for which it is used.

72. As a direct and legal result of the breach of warranty of fitness by the Defendants, Plaintiff suffered significant injuries and endured substantial pain and suffering and emotional distress. Plaintiff incurred, and will continue to incur, expenses for medical treatment, loss of capacity for the enjoyment of life, and other losses and damages recognized by Arkansas law. Plaintiff has been physically, emotionally, and economically injured and seeks all damages recoverable by law from the Defendants, as alleged herein.

73. WHEREFORE, Plaintiff demands judgment against the Defendants for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

COUNT IV
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

74. Plaintiff repeats, reiterates and realleges the allegations set forth in paragraphs 1 through 73 above, with the same force and effect as if fully set forth herein.

75. The Defendants violated the implied warranty of merchantability under Arkansas law.[3]

76. Defendants are a merchant with respect to the sale of pharmaceuticals.

77. Defendants' goods, Tequin, did not pass without objection in the trade under its contract description.

78. Tequin is a fungible good that could be interchanged with several other fluoroquinolone antibiotics and which was not of average quality within its contract description because it was unreasonably dangerous.

[3] *E.I. Du Pont de Nemours & Co. v. Dilaha*, 280 Ark. 477, 480 (Ark. 1983).

79. Because of its unreasonable dangerousness, Tequin is not fit for the ordinary purposes for which such goods are used.

80. Tequin did not run within the variations of quality and safety permitted.

81. Tequin was not adequately labeled and did not warn doctors or their patients that taking Tequin would significantly increase the patient's risk of developing diabetes or a severe blood sugar disorder.

82. When Defendants placed the drug into the stream of commerce, they knew of the use for which the drug was intended and impliedly warranted the products to be merchantable quality and safe fit for such use.

83. Plaintiff reasonably relied upon the expertise, skill, judgment and knowledge of Defendants and upon the implied warranty that the drug was of merchantable quality and fit for use for the treatment of respiratory illnesses in patients.

84. Because of his infection, the Plaintiff was a person whom the Defendants would have reasonably expected to use Tequin.

85. Tequin was not of merchantable quality because it was and is unreasonably dangerous and unfit for the ordinary purposes for which it was and is used.

86. As a direct and legal result of the breach of warranty of Defendants, i.e. the un-merchantable condition of Tequin, Plaintiff suffered physical injuries and endured substantial pain and suffering. He incurred, and will continue to incur, expenses for medical treatment, loss of capacity for the enjoyment of life and other losses and damages recognized by Arkansas law. Plaintiff has been physically, emotionally, and economically injured and seeks all damages recoverable by law from Defendants, as alleged herein.

87. WHEREFORE, Plaintiff demands judgment against the Defendants for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

COUNT V
FRAUDULENT MISREPRESENTATION

88. Plaintiff repeats, reiterates and realleges the allegations set forth in paragraphs 1 through 87 above, with the same force and effect as if fully set forth herein.

89. The Defendants false representations of material facts regarding Tequin's safety and efficacy that they knew were false or there was insufficient evidence upon which to make the representations.

90. The Defendants intended that Plaintiff and his doctors would rely on its false statements in the manner contemplated and act upon those statements.

91. Plaintiff and his doctors were unaware of the falsity of the Defendants' misrepresentations and justifiably acted on Defendants' misrepresentations and Plaintiff was injured as a direct result of the false statement.

92. Defendants fraudulently, intentionally and/or ignorantly misrepresented to the Plaintiff, his physician, and the general public the safety and effectiveness of the drug and/or fraudulently, intentionally and/or negligently concealed material, adverse information regarding the safety and effectiveness of the drug.

93. Defendants' misrepresentations were communicated to the prescribing physician and/or consumers with the intent that they reach the Plaintiff.

94. Defendants either knew or should have known that the representations were false.

95. Defendants made the misrepresentations and/or actively suppressed this information with the intention and specific desire that the Plaintiff, the prescribing physician or

other dispensing entities and the consuming public would rely on such in selecting the drug as treatment for infections and illness.

96. Defendants intentionally diluted and/or suppressed material, adverse information regarding the safety and effectiveness of their product.

97. Defendants misrepresented adverse information at a time when the Defendants knew, or should have known, that their drug product had defects, dangers, and/or characteristics that were other than what the Defendants had represented to the prescribing doctors or other dispensing entities, the FDA, and the consuming public, including the Plaintiff herein. Specifically, the Defendants misrepresented to Plaintiff, his prescribing physicians or other dispensing entities, the FDA and the consuming public:

a. That the drug was as safe as other quinolones in its class;

b. That it was safe to prescribe the drug to patients with diabetes;

c. That despite knowing that there had been insufficient or inadequate testing of the drug; the drug was marketed, promoted and/or sold as if it were full and adequately tested;

d. That there had been sufficient studies regarding the safety and efficacy of the drug for use in both diabetics and non-diabetics;

e. That although prior studies, research, reports and/or testing had been conducted linking the use of the drug, to serious adverse reactions including, but not limited to severe and life-threatening dysglycemia, hypoglycemia and/or hyperglycemia, that the drug was safe and effective for the treatment of infection;

f. That it knew, or should have known of adverse event reports, animal studies, case reports and other studies associating events of hypoglycemia, hyperglycemia, dysglycemia and death to the drug;

g. The nature and extent of beneficial health effect the drugs would provide the user.

h. That the drug was safe and efficient even though in reality it significantly increased the risk of diabetes and hypoglycemic and hyperglycemic episodes.

98. Defendants intentionally diluted its warnings and advertisements as to the dangerousness Tequin posed by (1) presenting confusing and contradictory information in its material; and (2) misrepresenting material facts.

99. The misrepresentations were perpetuated directly and/or indirectly by the Defendants, its sales representatives, employees, distributors, agents and/or detail persons.

100. The misrepresentations by the Defendants constitute a continuing tort.

101. Through Defendants' manufacturer product insert(s), the Defendants manufacturer continued to misrepresent the potential risks and complications associated with Tequin.

102. Defendants have a post-sale duty to warn Plaintiff about the potential risks and complications associated with Tequin in a timely manner.

103. Defendants misrepresented the safety and efficacy of the drug product in their labeling, advertising, product inserts, promotional materials, or other marketing efforts.

104. Plaintiff and/or the prescribing physician justifiably relied on and/or were induced by the misrepresentations of the Defendants to the Plaintiff's detriment.

105. As a consequent and proximate result of the intentional misrepresentations of the Defendants, Plaintiff suffered physical injuries and endured substantial pain and suffering. He incurred expenses for medical treatment, loss of capacity for the enjoyment of life and other losses and damages recognized by Arkansas law. Plaintiff has been physically, emotionally, and economically injured and seeks all damages recoverable by law from Defendants, as alleged herein.

106. WHEREFORE, Plaintiff demands judgment against the Defendants for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

COUNT VI
FRAUDULENT CONCEALMENT

107. Plaintiff repeats, reiterates and realleges the allegations set forth in paragraphs 1 through 106 above, with the same force and effect as if fully set forth herein.

108. Defendants suppressed and misrepresented material facts regarding Tequin's safety and efficacy that the Defendants had an obligation to communicate to Plaintiff and his doctor.

109. Defendants furtively planned and actively and secretly concealed information at a time when the Defendants knew, or should have known, that their drug product had defects, dangers, and/or characteristics that were other than what the Defendants had represented to the prescribing doctors or other dispensing entities, the FDA and the consuming public, including the Plaintiff herein. Specifically, the Defendants furtively planned and actively concealed and misrepresented the following material facts to the Plaintiff, his prescribing physicians or other dispensing entities, the FDA and the consuming public:

a. *The drug significantly increased the risk of, and could cause, diabetes.*

b. The drug should have been contraindicated for patients with diabetes;

c. The drug carried risks of serious adverse effects;

d. There had been insufficient studies regarding the safety and efficacy of the drug for use in both diabetics and non-diabetics;

e. Prior studies, research, reports and/or testing had been conducted linking the use of the drug, to serious adverse reactions, including, but not limited to severe and life-threatening dysglycemia;

f. Defendants knew, or should have known of adverse event reports, animal studies, case reports and other studies associating events of dysglycemia and death related to the drug; and

g. The number of deaths and severe blood reactions associated with Tequin.

110. The Defendants intended to induce the Plaintiff, his physician and the FDA to act on its suppression and misrepresentation of material facts.

111. The active concealment by the Defendants was perpetuated directly and/or indirectly by the Defendants, its sales representatives, employees, distributors, agents and/or detail persons.

112. The planned and active concealment by the Defendants constitutes a continuing tort.

113. Through Defendants' manufacturer product insert(s), the Defendant manufacturers' continued to misrepresent and suppress the potential risks and complications associated with Tequin.

114. Defendants have a post-sale duty to warn Plaintiff about the potential risks and complications associated with Tequin in a timely manner.

115. Defendants suppressed material facts as to the safety and efficacy of the drug product in their labeling, advertising, product inserts, promotional materials, or other marketing efforts.

116. To his detriment, Plaintiff and/or his prescribing physician justifiably relied on and were induced by the Defendants' suppression of material facts.

117. As a direct and legal result of the Defendants' suppression and misrepresentation of material facts, Plaintiff suffered physical injuries and endured substantial pain and suffering. He incurred expenses for medical treatment, loss of capacity for the enjoyment of life and other losses and damages recognized by Arkansas law. Plaintiff has been physically, emotionally, and economically injured and seeks all damages recoverable by law from the Defendants, as alleged herein.

118. WHEREFORE, Plaintiff demands judgment against the Defendants for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

COUNT VII
INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS[4]

119. Plaintiff repeats, reiterates and realleges the allegations set forth in paragraphs 1 through 118 above, with the same force and effect as if fully set forth herein.

120. Defendants acted intentionally or willfully and wantonly knew or should have known that emotional distress would likely result from their behavior, when they:

a. Designed, manufactured, tested, and/or supplied, and/or sold and distributed a defective product to Plaintiff;

b. Concealed and/or diluted the defects in Tequin from Plaintiff and his doctors; and

[4] *Croom v. Younts*, 373 Ark. 95, 100-101 (Ark. 1996); *see also McQuay v. Guntharp*, 331 Ark. 466, 470-471 (Ark. 1998).

c. Misrepresented the quality, safety, and usefulness of the drug.

121. Defendants' extreme and outrageous conduct directly impacted and directly involved Plaintiff in that he and/or his physicians decided to purchase, ingest, and/or use the defective and dangerous antibiotic, which Defendants manufactured, sold, and distributed, causing in Plaintiff to suffer and continue to suffer severe emotional distress.

122. Defendants' conduct, above, was extreme and outrageous and is intolerable in civilized society and beyond all possible bounds of decency.

123. As a direct result of Defendants' misconduct alleged herein, Plaintiff has developed diabetes, suffered a severe hypoglycemic reaction, suffered severe mental pain and anguish, expense and economic loss as previously described, all which no reasonable person could be expected to endure, rendering Defendants liable for all damages allowed by Arkansas law.

124. As a direct and legal result of the Defendants' intentional, outrageous conduct, Plaintiff suffered not only physical injuries and pain and suffering, but he also suffered severe emotional distress as well. Such distress is recognized as damages under Arkansas law. Plaintiff seeks recovery from Defendants for his emotional distress, as alleged herein.

125. WHEREFORE, Plaintiff demands judgment against the Defendants for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

COUNT VIII
VIOLATION OF ARKANSAS CONSUMER PROTECTION ACT/ DECEPTIVE TRADE PRACTICES[5]

126. Plaintiff repeats, reiterates and realleges the allegations set forth in paragraphs 1 through 125 above, with the same force and effect as if fully set forth herein.

[5] Arkansas Code § 48-88-101, *et. seq.*

127. Defendants violated Arkansas Code § 48-88-101, *et. seq.*, and specifically Arkansas Code § 48-88-107 and Arkansas Code § 48-88-108 when the acted deceptively, knowingly making false representations and concealing, suppressing and omitting material facts regarding the safety and efficacy of Tequin.

128. Defendants engaged in unfair and/or deceptive acts or practices when they knew or should have known they had in the past and/or were presently engaging in the following unfair acts:

a. Making false representations as to the characteristics, uses, and benefits of Tequin.

b. Making false representations regarding the grade, quality, safety, and usefulness of Tequin.

c. In connection with the sale of Tequin, the Defendants employed deception, fraud and false pretense as outlined in the above claim for Fraudulent Misrepresentation.

d. In connection with the sale of Tequin, the Defendants concealed, suppressed and omitted material facts related to Tequin's defects, safety and efficacy, as outlined in above Fraudulent Concealment claim, with the intent that others, including the Plaintiff and his physicians, would rely on the concealment, suppression and omission.

e. Designed, manufactured, tested, and/or supplied, and/or sold and distributed a defective product to Plaintiff;

129. Defendants knew or should have known in the exercise of due care that they were engaging in the above mentioned wrongful acts.

130. Plaintiff was deceived and harmed as a proximate result of the Defendants' unfair and/or deceptive practices. As a result, the Plaintiff is entitled to recover actual damages and reasonable attorneys' fees.

131. WHEREFORE, Plaintiff demands judgment against the Defendants for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

COUNT IX
PUNITIVE DAMAGES

132. Plaintiff repeats, reiterates and realleges the allegations set forth in paragraphs 1 through 131 above, with the same force and effect as if fully set forth herein.

133. In accordance with Arkansas Code § 16-55-206, the Plaintiff is entitled to punitive damages because one or both of the following factors were and related to his injury for which he is entitled to compensatory damages:

a. The Defendants knew or ought to have known that their conduct would naturally and probably result in injury or damage and they continued the conduct with malice or in reckless disregard of the consequences; or

b. The Defendants intentionally pursued a course of conduct for the purpose of causing injury or damage.

134. As a direct and legal result of the Defendants' reckless disregard of the consequences of their conduct that they knew or should have known would result in injury, did result in injury to the Plaintiff. Plaintiff suffered not only physical injuries and pain and suffering, but he also suffered severe emotional distress as well. Such punitive damages are recognized as damages under Arkansas law. Plaintiff seeks recovery from Defendants for their malicious and reckless conduct.

135. WHEREFORE, Plaintiff demands judgment against the Defendants for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

PLAINTIFF'S DAMAGES

136. As a result of the combined and concurring violation of Arkansas product liability law, strict liability, negligence, breach of implied warranties, fraudulent concealment, fraudulent misrepresentations, intentional infliction of emotional distress, violation of Arkansas Consumer Protection Acts/Unfair Trade Practices, and the design, sale, distribution and promotion of the defective product, Tequin, the above-named Defendants have caused or contributed to cause the following injuries to the Plaintiff:

a. Plaintiff has been caused to suffer, and will continue to suffer, physical injury, pain and suffering, and mental anguish;

b. Plaintiff has been caused to incur, and will continue to incur, medical expenses;

c. Plaintiff has incurred other consequential economic losses, including loss of income and the costs associated with this lawsuit.

137. WHEREFORE, Plaintiff demands judgment against the Defendants, of all kinds and nature as are allowed by law, for all of the counts and causes alleged above, for compensatory and punitive damages, in such an amount as may be awarded to the Plaintiff by a jury.

JURY TRIAL DEMAND

Plaintiff hereby demands a jury trial in this matter.

CLYDE OWEN,
PLAINTIFF, by his attorneys,

David S. Nalven, DN-2374
Kimberly A. Dougherty
HAGENS BERMAN SOBOL SHAPIRO LLP
One Main Street, 4th Floor
Cambridge, MA 02142
Telephone: (617) 482-3700
Facsimile: (617) 482-3003

Robert B. Carey
Donald Andrew St. John
HAGENS BERMAN SOBOL SHAPIRO LLP
2425 E. Camelback Road, Suite 650
Phoenix, Arizona 85016
Telephone: (602) 840-5900
Facsimile: (602) 840-3012

Dated: August 20, 2007